4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 20

[Docket No. FDA-2012-N-0205]

Agreements and Memoranda of Understanding Between the Food and Drug Administration and Other Departments, Agencies, and Organizations

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: This final rule makes technical changes that will update a requirement that many of the written agreements and memoranda of understanding (MOUs) between the Food and Drug Administration (FDA) and other departments, Agencies, and organizations be published in the Federal Register. Because we already post and will continue to post our ongoing agreements and MOUs with other departments, Agencies, and organizations on our Web site upon their completion, this requirement is no longer necessary. This final rule, accordingly, eliminates it. We are making these technical changes to conserve Agency time and resources, reduce government paperwork, and eliminate unnecessary Federal Register printing costs while continuing to afford public access to these documents.

DATES: This rule is effective [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Rulemaking Procedure

In the Federal Register of March 23, 2012 (77 FR 16923), FDA published a direct final rule to eliminate the requirement that many of our written agreements and MOUs with other departments, Agencies, and organizations be published in the Federal Register. We explained that we issued this rule as a direct final rule because we believed it was noncontroversial and did not anticipate receiving significant adverse comments. We concurrently published in the Federal Register of March 23, 2012 (77 FR 16971) a companion proposed rule, substantively identical to the direct final rule, that provided a procedural framework from which to proceed with standard notice-and-comment rulemaking in the event we were required to withdraw the direct final rule because of significant adverse comments. A significant adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without change. Any comments received under the companion proposed rule were treated as comments regarding the direct final rule and vice versa. A full description of FDA's policy on direct final rule procedures may be found in a guidance document published in the Federal Register of November 21, 1997

(62 FR 62466). This guidance document may be accessed at http://www.fda.gov/RegulatoryInformation/Guidances/ucm125166.htm

We received one comment on the proposed rule, which we considered significantly adverse. Therefore, in the Federal Register of June 27, 2012 (77 FR 38173), we withdrew the direct final rule. This final rule summarizes and responds to this comment on the direct final rule and proposed rule. See section IV of this document for a discussion of the comment and FDA's response.

II. Background

In the Federal Register of October 3, 1974 (39 FR 35697), we announced that copies of all our MOUs transacted with government Agencies and nongovernment organizations were available for public review at our offices during working hours and would be published in the Federal Register. We subsequently codified this policy in the Federal Register of December 24, 1974 (39 FR 44602 at 44651) and recodified it where it currently appears at § 20.108 (21 CFR 20.108) in the Federal Register of March 22, 1977 (42 FR 15616 at 15625).

Consumers, industry, professional groups, associations, educators, and other government Agencies had manifested widespread interest in the texts of these MOUs. The intent of § 20.108 was to promote transparency by providing access to these stakeholders.

III. Summary of the Final Rule

This final rule will eliminate the requirement in current § 20.108(c) that our agreements and MOUs with other departments, Agencies, and organizations be published in the Federal Register on an individual basis and instead will require that they be posted on our Web site as completed. We increasingly rely on Internet-based communications to ensure and promote transparency in our operations and activities. So it is with this final rule, which merely

recognizes and codifies our already established practice of making our ongoing agreements and MOUs with other departments, Agencies, and organizations publicly available on our Web site. At the time of this writing, each such publicly disclosable agreement and MOU can be accessed at one of the following three FDA Web site locations: http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/default.htm; http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/AcademiaMOUs/default.htm; or http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/OtherMOUs/default.htm.

Because all publicly disclosable agreements and MOUs are posted on our Web site, it is no longer necessary to require, as does current § 20.108(b), that a permanent file of them be available for public review during working hours in the Agency's Freedom of Information Public Reading Room. Accordingly, this rule will revise current § 20.108(b).

The public's access to an FDA Web site that is regularly updated to include agreements and MOUs as they are completed has already greatly enhanced the speed, ease, and convenience with which stakeholders can obtain and review these documents.

The rule's technical changes will lessen demands on the time of our staff and reduce the government paperwork and printing costs associated with Federal Register publication of newly completed agreements and MOUs with other departments, Agencies, and organizations. At the same time, it will continue to ensure, consistent with the underlying intent of § 20.108, the accessibility of records of widespread interest to consumers, industry, professional groups, associations, educators, and other government Agencies.

Currently, § 20.108(c) treats our cooperative work-sharing agreements with State or local government Agencies differently from our agreements and MOUs with other Agencies and organizations. Because these cooperative work-sharing agreements rarely vary significantly from one another, we decided against publishing their full texts in the Federal Register (51 FR 19851; June 3, 1986). Instead, since 1993, we have merely required them to be listed at least once every 2 years in the Federal Register (58 FR 48794; September 20, 1993). This final rule will end such disparate treatment. Revised § 20.108(b) will apply to all of our written agreements and MOUs with other departments, Agencies, and organizations, including cooperative work-sharing agreements with State or local government Agencies, except for signed agreements and MOUs relating to activities of our Office of Criminal Investigations, which are addressed in § 20.108(d), which will be revised and redesignated as § 20.108(c).

This final rule does not amend § 20.108(a) (stating that our written agreements and MOUs are available for public disclosure).

IV. Comment on the Proposed Rule and FDA's Response

We received one comment on the proposed rule. A summary of that comment and FDA's response follow.

(Comment 1) While acknowledging "FDA's efforts to reduce printing costs associated with publication of newly completed" agreements and MOUs, the comment urged that such documents be published in full in the Federal Register, as they constitute "vital aspects of FDA's mission," and the Federal Register has been designated as the one place where important governmental actions can be found. The comment maintained that the Federal Register embodies a permanently available historical record providing potentially necessary details for recreating Agency thinking or policy at a given time. By contrast, the comment continued, FDA

removes obsolete documents from its Web site as it continuously updates it, thereby rendering that Web site unreliable as an Agency historical record. It additionally contended that on numerous occasions when FDA has updated its Web site, information has become difficult to find or links no longer connect to appropriate Web site pages.

(Response) We believe that the burden and costs imposed by Federal Register publication of agreements and MOUs, which include not only the printing costs acknowledged by the comment, but also the time of FDA staff and associated government paperwork, outweigh any arguable interest in reproducing these documents in their entirety in the Federal Register. To the extent that any of these documents are eventually no longer accessible on FDA's Web site, they, like numerous other significant documents that are not reprinted in the Federal Register, constitute permanent Agency records required to be archived and made available to the public on request.

V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this final rule is not a significant regulatory action under Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule does not

impose any significant costs, we certify that it will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $139 million, using the most current (2011) Implicit Price Deflator for the Gross Domestic Product. We do not expect this rule to result in any 1-year expenditure that would meet or exceed this amount.

VI. Paperwork Reduction Act of 1995

We have concluded that this final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520) is not required.

VII. Environmental Impact

We have determined under 21 CFR 25.33 that this final rule is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. We have determined that this final rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of

government. Accordingly, we have concluded that this final rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

List of Subjects in 21 CFR Part 20

Confidential business information, Courts, Freedom of information, Government employees.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 20 is amended as follows:

PART 20--PUBLIC INFORMATION

1. The authority citation for 21 CFR part 20 continues to read as follows:

Authority: 5 U.S.C. 552; 18 U.S.C. 1905; 19 U.S.C. 2531-2582; 21 U.S.C. 321-393, 1401-1403; 42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b-263n, 264, 265, 300u-300u-5, 300aa-1.

2. Section 20.108 is amended as follows:

a. Revise paragraph (b);

b. Remove paragraph (c);

c. Redesignate paragraph (d) as paragraph (c);

d. Revise newly redesignated paragraph (c).

The revisions read as follows:

§ 20.108 Agreements between the Food and Drug Administration and other departments, agencies, and organizations.

* * * * *

(b) All written agreements and memoranda of understanding between FDA and any entity, including, but not limited to other departments, Agencies, and organizations will be made available through the Food and Drug Administration Web site at http://www.fda.gov once finalized.

(c) Agreements and understandings signed by officials of FDA with respect to activities of the Office of Criminal Investigations are exempt from the requirements set forth in paragraph (b) of this section. Although such agreements and understandings will not be made available through the FDA Web site, these agreements will be available for disclosure in response to a request from the public after deletion of information that would disclose confidential investigative techniques or procedures, or information that would disclose guidelines for law enforcement investigations if such disclosure could reasonably be expected to risk circumvention of the law.

Dated: August 17, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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